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<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/086,933	KLEIN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jean C. Witz	1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to response filed 11/8/04.
2. ☒ The allowed claim(s) is/are 1-7 and 9-25.
3. ☒ The drawings filed on 01 March 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                       |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                               |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance                         |
|   | 9. <input type="checkbox"/> Other _____.  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I in the reply filed on November 8, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. In further review of the claims, the restriction requirement has been redrawn as set forth below. Applicants are advised that since 37 CFR 1.142(a) provides that restriction is proper at any stage of prosecution up to final action, a second requirement may be made when it becomes proper, even though there was a prior requirement with which applicant complied. *Ex parte Benke*, 1904 C.D. 63, 108 O.G. 1588 (Comm'r Pat. 1904).
3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-7, 9-25, drawn to methods of preparing immunologically inert and implantable graft material, classified in class 435, subclass 1.2.
  - II. Claims 26-33, drawn to a method of preparing an immunologically inert graft material, classified in class 435, subclass 1.2.
  - III. Claim 8, drawn to an immunologically inert graft material, classified in class 424, subclass 543.

The inventions are distinct, each from the other because of the following reasons:

4. Inventions I and II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1)

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the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the graft can be made by a materially different process such as the use of antibodies to render the antigens inactive or the reconstitution of an extracellular matrix with its individual components..

5. Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because Invention I does not require the cyclic osmotic treatment. The subcombination has separate utility such as a method of cleaning and bleaching plastic articles such as disclosed in U.S. Patent 3,908,680.

6. Because these inventions are distinct for the reasons given above and the search required for one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

7. During a telephone conversation with Shawn Dempster on March 14, 2005, an election was made without traverse to prosecute the invention of Group I, claims 1-7 and 9-25. Claims 8 and 26-33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### **EXAMINER'S AMENDMENT**

9. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Shawn Dempster on March 14, 2005.

The application has been amended as follows:

#### **IN THE CLAIMS:**

Claim 1 has been amended to read:

1. A method of preparing an immunologically inert collagenic graft material comprising the steps of:

procuring body tissue from one of an autologous, heterologous or allogenic source;

soaking the body tissue in a bleach solution;

rinsing the body tissue in water to remove bleach solution from the tissues;

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washing the body tissue in a detergent solution;  
rinsing the body tissue to remove the detergent solution;  
trimming the body tissue to a desired physical form;  
soaking the body tissue in an iodophor solution;  
rinsing the body tissue to remove the iodophor solution;  
soaking the body tissue in a hypertonic solution;  
rinsing the body tissue to remove the hypertonic solution therefrom;  
agitating the body tissue in a caustic solution;  
rinsing the body tissue in water under agitation to remove the caustic solution therefrom;  
treating the body tissue with a peroxide solution under agitation;  
rinsing the body tissue in sterile water; and  
conserving the body tissue in a sterile environment until needed.

Claim 4, line 3, the term "and" has been replaced by the term "or".

Claim 5, line 3, the term ".75 N" has been replaced by the term "0.75 N" and the term "1.25N" has been replaced by the term "1.25 N".

Claims 9-10 have been amended to read:

9. A method of preparing an immunologically inert collagenic graft material comprising the steps of:  
procuring body tissue from one of an autologous, heterologous or allogenic

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source;

washing the body tissue in a detergent solution;

treating the body tissue with at least one anti-microbial and/or anti-viral solution;

soaking the body tissue in a hypertonic solution;

soaking the body tissue in a solution comprising a caustic reagent;

treating the body tissue with a hydrogen peroxide solution; and

conserving the body tissue in a sterile environment.

10. A method of preparing an implantable collagenic graft material by removing cellular components from a preexisting extracellular matrix comprising the steps of:

freezing and subsequently thawing an untreated portion of the extracellular matrix in a bleach solution;

washing the extracellular matrix in a detergent solution;

lysing cellular components present in the extracellular matrix by soaking the extracellular matrix in a hypedonic solution',

soaking the extracellular matrix in a solution of sodium hydroxide; and

soaking the extracellular matrix in a solution of hydrogen peroxide.

Claim 16, line 3, the term "and" has been replaced by the term "or".

Claim 17, line 2, the term "and" has been replaced by the term "or".

Claim 18 has been amended to read:

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18. The method of preparing an immunologically inert graft material of claim 9 wherein the anti-microbial and/or anti-viral solution comprises one of povidone-iodine, sodium hypochlorite, or calcium hypochlorite.

Claim 19, line 3, the term "and" has been replaced by the term "or".

Claim 20, line 2, the term "or" has been inserted after the term "sodium peroxide,".

Claim 21, line 2, the term "and" has been replaced for the term "or".

Claim 24, line 2 and line 4, the term "tissues" has been replaced by the term "tissue".

10. This application is in condition for allowance except for the presence of claims 8 and 26-33, drawn to Inventions II and II, non-elected without traverse. Accordingly, claims 8 and 26-33 have been cancelled without prejudice to the filing of a divisional application.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See U.S. Patent 5,756,678 to Shenoy et al. which discloses the state of the art in connective tissue treatment.


12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (571) 272-0927. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jean C. Witz  
Primary Examiner  
Art Unit 1651